

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INO THERAPEUTICS LLC and IKARIA,)	
INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
PRAXAIR DISTRIBUTION, INC. and)	
PRAXAIR, INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs INO Therapeutics LLC (hereinafter “INOT”), and Ikaria, Inc. (hereinafter “Ikaria”) (collectively, “Plaintiffs”) for their Complaint against defendants Praxair Distribution, Inc. and Praxair, Inc. (collectively “Praxair” or “Defendants”), hereby allege as follows:

THE PARTIES

1. Plaintiff INOT is a wholly-owned subsidiary of Ikaria and is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at Perryville III Corporate Park, P. O. Box 9001, 53 Frontage Road, Third Floor, Hampton, New Jersey 08827-9001.

2. Plaintiff Ikaria is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Perryville III Corporate Park, P.O. Box 9001, 53 Frontage Road, Third Floor, Hampton, New Jersey 08827-9001.

3. Plaintiff Ikaria is a research-driven healthcare company that discovers, develops, manufactures and markets innovative products to address the needs of critically ill patients.

4. On information and belief, Praxair Distribution, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its head office at 28 McCandless Ave, Pittsburgh, Pennsylvania 15201.

5. On information and belief, Praxair, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 39 Old Ridgebury Road, Danbury, Connecticut 06810.

6. On information and belief, Praxair Distribution, Inc. is a wholly-owned subsidiary of Praxair, Inc.

7. On information and belief, Praxair Distribution, Inc. assembled and caused to be filed with the United States Food and Drug Administration (“FDA”), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application (“ANDA”) No. 207141 (hereinafter “the Praxair ANDA”) concerning a proposed drug product, Noxivent, 100 ppm and 800 ppm nitric oxide for inhalation (“Praxair’s Proposed ANDA Product”).

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Praxair Distribution, Inc. On information and belief, Praxair Distribution, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Praxair Distribution, Inc. maintains a corporate agent for service of process at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

10. This Court also has personal jurisdiction over Praxair, Inc. On information and belief, Praxair, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Praxair, Inc. maintains a corporate agent for service of process at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

11. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391 and 1400(b).

INOmax[®] (NITRIC OXIDE) FOR INHALATION

12. INOT holds approved New Drug Application (“NDA”) No. N020845 for nitric oxide 100 and 800 ppm for inhalation to among other things treat neonates with pulmonary hypertension, and is prescribed and sold in the United States under the trademark INOmax[®]. The U.S. Food and Drug Administration (“FDA”) approved NDA No. N020845 on December 23, 1999.

THE PATENTS-IN-SUIT

13. United States Patent No. 8,282,966 (the “’966 patent,” copy attached as Exhibit A) is entitled “Methods of Reducing the Risk of Occurrence of Pulmonary Edema in Children in Need of Treatment with Inhaled Nitric Oxide” and was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on October 9, 2012. The ’966 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) for INOmax[®] (NDA No. N020845).

14. The ’966 patent is owned by INOT.

15. United States Patent No. 8,293,284 (the “’284 patent,” copy attached as Exhibit B) is entitled “Methods of Reducing the Risk of Occurrence of Pulmonary Edema in Term or Near-Term Neonates in Need of Treatment with Inhaled Nitric Oxide” and was duly and

legally issued by the USPTO on October 23, 2012. The '284 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

16. The '284 patent is owned by INOT.

17. United States Patent No. 8,431,163 (the "'163 patent," copy attached as Exhibit C) is entitled "Methods of Reducing the Risk of Occurrence of Pulmonary Edema Associated with the Inhalation of Nitric Oxide Gas" and was duly and legally issued by the USPTO on April 30, 2013. The '163 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

18. The '163 patent is owned by INOT.

19. United States Patent No. 8,795,741 (the "'741 patent," copy attached as Exhibit D) is entitled "Methods For Treating Patients Who Are Candidates For Inhaled Nitric Oxide Treatment" and was duly and legally issued by the USPTO on August 4, 2014. The '741 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

20. The '741 patent is owned by INOT.

21. United States Patent No. 8,846,112 (the "'112 patent," copy attached as Exhibit E) is entitled "Methods Of Distributing A Pharmaceutical Product Comprising Nitric Oxide Gas For Inhalation" and was duly and legally issued by the USPTO on September 30, 2014. The '112 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

22. The '112 patent is owned by INOT.

23. United States Patent No. 8,291,904 (the "'904 patent," copy attached as Exhibit F) is entitled "Gas Delivery Device And System" and was duly and legally issued by the USPTO on October 23, 2012. The '904 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

24. The '904 patent is owned by INOT.

25. United States Patent No. 8,573,210 (the "'210 patent," copy attached as Exhibit G) is entitled "Nitric Oxide Delivery Device" and was duly and legally issued by the USPTO on November 5, 2013. The '210 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

26. The '210 patent is owned by INOT.

27. United States Patent No. 8,573,209 (the "'209 patent," copy attached as Exhibit H) is entitled "Gas Delivery Device And System" and was duly and legally issued by the USPTO on November 5, 2013. The '209 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

28. The '209 patent is owned by INOT.

29. United States Patent No. 8,776,794 (the "'794 patent," copy attached as Exhibit I) is entitled "Nitric Oxide Delivery Device" and was duly and legally issued by the USPTO on July 15, 2014. The '794 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

30. The '794 patent is owned by INOT.

31. United States Patent No. 8,776,795 (the "'795 patent," copy attached as Exhibit J) is entitled "Gas Delivery Device and System" and was duly and legally issued by the USPTO on July 15, 2014. The '795 patent is listed in the FDA's Orange Book for INOmax[®] (NDA No. N020845).

32. The '795 patent is owned by INOT.

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